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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,553	02/16/2001	Ming-Ming Zhou	2459-1-003 CIP	3124
23565	7590	02/22/2006	EXAMINER	
KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601			LUCAS, ZACHARIAH	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/784,553

Applicant(s)

ZHOU ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 9-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Currently, claims 1-36 are pending in the application.
2. In the prior action, the Final action mailed on August 10, 2005, claims 5-8 were rejected, and claims 1-4 and 9-36 stood withdrawn as to non-elected inventions.
3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection on December 28, 2005. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 10, 2005 has been entered.

In the submission entered upon the filing of the RCE, the Applicant amended claims 5 and 7.

Claim Objections

4. **(New Objection)** Claims 6 and 8 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 8 is treated as representative. Claim 7, from which claim 8 purports to depend, reads on a peptide consisting of a ZA loop of a bromodomain having between 12-40 amino acids. Thus, the claim is limited to peptides consisting of the ZA loop. However, claim 8 reads on a fusion protein or peptide comprising the peptide of claim 7. As indicated in MPEP § 608.01(n), "The test as to whether a claim is a proper dependent claim is that it shall include every limitation of the claim

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from which it depends.” In the present claim 7 excludes the presence of any sequence other than the ZA loop sequence, whereas claim 8 requires the presence of such other sequences. The same applies with respect to the dependency of claim 6 from claim 5. Thus, claims 6 and 8 are not properly dependant on claims 5 or 7.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

For the purposes of this action, unless otherwise indicated, claim 8 is treated as though it was drafted in independent form.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. **(Prior Rejection- Maintained)** Claims 5-8 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims read on peptides comprising the ZA loop of protein bromodomains that fall within an indicated generic structure, that of SEQ ID NO: 3. The claims were rejected as the application does not teach how to use the claimed peptides.

The claimed genus of peptides includes peptides with a variety of structures, and which interact with a number of different proteins (some of which are known) and are involved in a

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number of different biological activities. See e.g., App., page 3, and the Declaration of Ming-Ming Zhou, PhD (Zhou Declaration). for those peptides for which binding partners are known, each of the peptides interacts with different ligands, and is involved with a different biological process. Zhou Declaration, pages 2-4. Thus, in order to be enabling for the full scope of the claimed invention, the application must teach how to use each of the claimed peptides. This is because, in the present case, there is no functional relationship among the various claimed peptides. Thus, to be enabling for the full scope of the claimed peptides, the application must teach how to use each of these peptides.

In the present application, the teachings are simply not sufficient to enable those in the art to use each of the claimed peptides. For the majority of the proteins, there is no identification of either a ligand or a biological function performed by the protein from which the peptides was derived. Further, in the case of the elected Ring3 protein, while the art indicates that the protein may be involved with cancer, the nature of this involvement is not clear. Thus, those in the art would not know if the peptide or its modulators would up or down regulate the activity of its ligands, and would therefore not know how to use them.

In addition, the claims as newly amended require the screening for inhibitors with any peptides comprising an acetyl lysine. As was indicated above, because the only use for the claimed peptides is for the identification of such modulators, in order to use the claimed peptides those in the art would need to know what lysine containing peptides and proteins to use. However, because the application and art indicate that each bromodomain binds different ligands, and that such ligands vary depending from bromodomain to bromodomain (see e.g., Zhou declaration), and according to the sequence surrounding the acetyl lysine (see e.g., action

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of August 2005, pages 5 and 9), and as the ligands for many of the claimed peptides are unknown, this functional language does not provide any limiting information to demonstrate enablement of the claimed peptides. Those in the art would have not been provided information with respect to which bromodomain peptides would bind to which acetyl lysine containing peptides. Thus, along with failing to teach how to use modulators of the indicated interactions, the application also fails to enable the practice of the indicated assays, as there is no guidance as to what peptides containing an acetyl lysine would bind to any particular of the claimed peptides.

The Applicant asserts that enablement does not require knowledge of how a claimed invention works. While this is technically true, enablement does require a teaching as to how to use the claimed invention. For example, in the present case, the application nowhere demonstrates the actual effect that the Ring3 peptide would have in any particular condition or biological activity. Because the application nowhere provides any such demonstration as to effect of the peptide, the only source that those in the art would have for determining how to use the peptide would be what the art describes as its function. Thus, absent a demonstration of its effect, and thus how to use the peptide, the enabling support must be found elsewhere if at all. One such source would be a teaching as to the biological activity of the peptide such that those in the art would then know the operation of the peptide, and thus how to use it, or its modulators.

As the application neither demonstrates how to use the claimed Ring3 peptide, nor any other peptide (except perhaps the non-elected P/CAF peptide), then the only other means for demonstrating enablement would be either such a demonstration in the art, or a teaching in the art as to the function of the protein. In the present case, as the art provides neither as was

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described in the prior actions. Thus, there is insufficient information provided for those in the art to use the claimed peptides (including the elected Ring3 peptide) or their modulators.

It is additionally noted that many of the teachings relied on by the Applicant to establish the knowledge in the art are from references post-dating the present application. As such, these references do not present information on which the Applicant may rely to show what was known in the art at the time the application was filed. Rather, they provide new information on which the application cannot now rely to demonstrate uses that have no support in the application as filed.

For these reasons, and the reasons of record, the rejection is maintained.

7. **(Prior Rejection- Withdrawn)** Claims 5-8 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims were drawn to peptides useful for the screening of inhibitors of interaction between a bromodomain and an acetylated lysine. The claims were rejected because the teachings in the art and the application indicate that the peptides do not interact with lone acetylated lysines, and thus the claims could not be enabling for claims requiring such interaction. The claims have now been amended to read on peptides useful for the screening of modulators between the claimed peptides and an acetylated lysine in a peptide or protein. The rejection is therefore withdrawn.

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8. **(Prior Rejection- Withdrawn)** Claims 5-8 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claim s have been amended to read on isolated peptides comprising a ZA loop of a bromodomain, wherein such peptides are useful for the identification of agents that may be used to “prevent HIV replication.” The indicated function has been deleted from the claims. The rejection is therefore withdrawn.

9. **(Prior Rejection- Withdrawn)** Claims 5-8 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This was a New Matter rejection. These claims read on peptides useful for screening for inhibitors that may be used to “inhibit tumor cell growth,” and were rejected lacking descriptive support for such a functional limitation. In view of the cancellation of the indicated language, the rejection is withdrawn.

10. **(Prior Rejection- Withdrawn)** Claims 5-8 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims read on isolated peptides comprising the ZA loop of a bromodomain, particularly to bromodomains of the formula of SEQ ID NO: 3, and more particularly to that of the RING3 protein (SEQ ID NO: 19), wherein such peptides may be used for screening of inhibitors of binding between the bromodomain and an acetylated lysine, and wherein such inhibitors inhibit tumor cell growth.

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The claims were rejected as not enabled for peptides with the indicated function. In view of the cancellation of the function from the claims, the rejection is withdrawn.

11. **(Prior Rejection- Withdrawn)** Claims 5-8 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. These claims were drawn to a genus of peptides identified by their falling within the formula of SEQ ID NO: 3, and by their functional activity as useful for the identification of inhibitors of HIV replication or tumor cell growth. In view of the cancellation of the indicated functional limitations, the rejection is withdrawn.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. **(Prior Rejection- Withdrawn)** Claims 5 and 6 were rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al., Nature 382: 319-24. The claims have been amended to read on a peptide comprising a ZA loop of a bromodomain, wherein the ZA loop consists of SEQ ID NO: 3. In view of the amendment of the claims to read on peptides consisting of SEQ ID NO: 3, the rejection is withdrawn.

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14. **(Prior Rejection- Maintained in part)** Claims 5-8 were rejected under 35 U.S.C. 102(b) as anticipated by Denis and Green (Genes Dev 10(3): 261-71). The claims and the teachings of Denis and Green have been previously described. Claims 5 and 7 have been amended to read on isolated peptides consisting of the ZA loops described therein. However, claims 6 and 8 read on fusion proteins comprising the isolated peptide of claims 5 and 7, and therefore read on any fusion protein comprising the ZA loop from SEQ ID NO: 19. As was previously described, the identified reference teaches such a fusion protein. The rejection is therefore maintained with respect to claims 6 and 8.

It is suggested that the claims be amended to include language such as the following: - -
A fusion protein or peptide consisting of a first sequence consisting of a ZA loop of a bromodomain according to SEQ ID NO: 19, and a second sequence from another protein.”

Conclusion

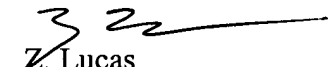
15. No claims are allowed.


16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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2/20/06